MAY 1 4 2014

510(K) Summary of Safety and Effectiveness K140591

Date Prepared: 4 March 2014

1. **Submitted By:**

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2. **Device Name:**

Trade Name:	BD PhaSeal Closed System Transfer Device – Injector
Common Name:	Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name:	Intravascular administration set
Classification:	Class II, 21 C.F.R. § 880.5440

3. **Predicate Device**

BD PhaSeal® Connector, Injector, Protector – K123213

4. **Device Description:**

The PhaSeal® System is a sterile single-use closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes for the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizing the risk of microbial contamination.

The PhaSeal Injector is one component of the PhaSeal system. It is a luer device adaptor that may be fitted to a syringe or IV tubing. It is used to gain dry and leak-proof access to a drug container or administration device which has been sealed with a PhaSeal Protector or Connector. Liquid transfer takes place through tightly fitting elastomeric double membranes to minimize exposure to potentially hazardous drug aerosols and spills occurring during reconstitution, administration and disposal processes.

5. **Intended Use**

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

6. **Technological Characteristics**

The technological characteristics referenced in Table 1: Technological Characteristics below have been modified from the predicate device. The results of design verification demonstrate that these characteristics are substantially equivalent to the predicate device. All other the technological characteristics of the subject device are identical to those of the predicate devices.

Table 1: Technological Characteristics

Subject	**Predicate (K123213)**	**Modified Device (N30C, N35, N35C)**	**Equiv.**
Injector membrane	Thermoplastic Elastomer (TPE)	TPE w/ silicone lubricant	Yes

7. **Performance**

Design Verification tests were performed based on the risk analysis performed, and the results of these tests demonstrate that the BD PhaSeal Closed System Transfer Device – Injector (N30C, N35, N35C) performed in an equivalent manner to the predicate device and is safe and effective when used as intended. Design Verification testing included the following:

Table 2: Design Verification Testing

Characteristic	**Test Performed**	**Result**
Biocompatibility	Per ISO 10993	Per ISO 10993
Membrane Leakage	Dye Leak Test	Equivalent to Predicate
Membrane Fragmentation	Fragmentation Test	Equivalent to Predicate

8. **Conclusion**

Based on comparison to the predicate device and the results of design verification testing, the modified BD PhaSeal® Closed System Drug Transfer Device – Injector (N30C, N35, N35C) is as safe, as effective, and performs as well as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

Becton, Dickinson and Company
Mr. John Roberts
Regulatory Affairs Specialist
1 Becton Drive MC237
FRANKLIN LAKES, NJ 07417

Re: K140591
Trade/Device Name: BD PhaSeal Closed System Transfer Device - Injector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: ONB
Dated: April 17, 2014
Received: April 21, 2014

Dear Mr. Roberts,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140591

Device Name
BD PhaSeal Closed System Transfer Device - Injector

Indications for Use *(Describe)*
The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.05.14 07:44:46 -04'00'

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